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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

IN RE: DA VINCI SURGICAL ROBOT ANTITRUST LITIGATION	Lead Case No.: 3:21-cv-03825-VC
THIS DOCUMENT RELATES TO: [ALL ACTIONS]	**INTUITIVE SURGICAL INC.'S MOTION TO EXCLUDE TESTIMONY OF KIMBERLY A. TRAUTMAN** Hearing Date: June 8, 2023 Hearing Time: 1:00 PM PST Hearing Place: Courtroom 4 Judge: The Honorable Vince Chhabria

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NOTICE OF MOTION AND MOTION

TO ALL PARTIES AND THEIR COUNSEL OF RECORD:

PLEASE TAKE NOTICE that on June 8, 2023, at 1:00 PM, or as soon thereafter as available, in the courtroom of the Honorable Vince G. Chhabria, located at 450 Golden Gate Avenue, Courtroom 4, 17th Floor, San Francisco, CA, 94102, Defendant Intuitive Surgical, Inc. will and hereby does move for an order excluding certain opinions of Kimberly A. Trautman, proffered as an expert witness for Plaintiffs. This Motion is based on this Notice of Motion and Memorandum of Points and Authorities, the accompanying Declaration of Andrew Lazerow and attached exhibits, any reply or other supplemental briefing and/or evidence submitted, and the oral argument of counsel.

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION AND STATEMENT OF ISSUE

Defendant Intuitive Surgical, Inc. ("Intuitive") respectfully submits this motion pursuant to Rule 702 of the Federal Rules of Evidence and *Daubert v. Merrell Down Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), to exclude the opinions of Kimberly A. Trautman ("Trautman"), proffered by Plaintiffs to opine as an expert on whether third parties who modify used EndoWrists to extend their use limits beyond their original FDA clearance "faced any regulatory bar" from the U.S. Food and Drug Administration ("FDA"). Lazerow Dec. Ex. 1 ¶ 6.[1] There is no dispute that third parties that engaged in this activity did ***not*** have FDA clearance. The fundamental question in this case, therefore, is whether this activity is "repair" or "servicing" (for which no FDA clearance is required) or "remanufacturing" (which cannot be lawfully performed without FDA clearance). This motion challenges Trautman's two fundamental opinions:

(1) She opines that a third party modifying an EndoWrist to circumvent its use counter is not a "remanufacturer" under FDA regulations, and thus does not require FDA clearance for such activity. *Id.* ¶¶ 30, 82, 83.

(2) She further opines that two of the third parties that engaged in this activity – Rebotix and Restore – did not introduce modified EndoWrists "into commercial distribution." *Id.* ¶ 30.

[1] Intuitive reserves the right to raise additional objections to Ms. Trautman's testimony at a later date. This motion focuses on issues fit for resolution at this stage of the case.

Plaintiffs cannot demonstrate that these opinions are admissible under Rule 702. Most fundamentally, both are legal conclusions. It is well-established that an expert must confine her opinions to matters that will aid the fact-finder in evaluating record evidence. Trautman instead offers her view on the legal issues of who qualifies as a "remanufacturer" under 21 C.F.R. § 820.3(w) and what constitutes "commercial distribution" under 21 C.F.R. § 807.81. These two issues have significant legal implications because remanufacturers of EndoWrists whose remanufactured products are in commercial use are required to first obtain 510(k) clearance under FDA regulations. Two courts in Florida facing similar proffered testimony in cases involving the activities of Rebotix and Restore excluded legal opinions from FDA regulatory experts on whether modifying EndoWrists to extend their use limits beyond their original clearance requires further clearance from FDA. Trautman has done nothing to heed these decisions. In fact, she does exactly what one court expressly warned against – espousing her own, personal interpretations of FDA regulations ***that differ from*** the interpretations consistently articulated by FDA officials themselves. And on the interpretation of "commercial distribution," the Ninth Circuit has already offered its own interpretation; even if Trautman genuinely believes the Ninth Circuit was wrong, it would be highly inappropriate for her to tell the jury that. In short, Plaintiffs cannot demonstrate that Trautman's opinions will be helpful to the jury in this case because they are matters within the province of this Court and the FDA.

Trautman's opinion that modifying an EndoWrist use counter is not "remanufacturing" under FDA regulations suffers from two additional fatal flaws. *First*, Trautman lacks sufficient qualifications to give this opinion. Trautman's experience is in international regulatory compliance. Although she was involved in drafting the 1996 Quality System regulation that, among other things, defines "remanufacturing," there is no dispute about the definition of that term in this case and, in any event, that regulation does ***not*** govern FDA clearance or the 510(k) approval pathway. Indeed, even when she worked as an FDA compliance officer on FDA enforcement actions, Trautman did not determine whether FDA clearance was required for particular devices; those determinations were made by others with expertise in the 510(k) clearance process. And her experience has not changed since leaving the

FDA, as she has never advised any consulting clients on the distinctions between "servicing" and "remanufacturing." She has only advised original equipment manufacturers (not potential remanufacturers) on whether modifications to a finished medical device – which are governed by a completely different standard – require FDA clearance.

Second, Trautman's opinion on whether the activities at issue in this case qualify as remanufacturing is unreliable. Trautman did not consider numerous statements by FDA officials that third party modifications to EndoWrists to extend their use limits qualify as "remanufacturing" and require 510(k) clearance. These statements were made repeatedly and consistently over the course of nearly a decade by FDA officials who (unlike Trautman during her FDA employment) ***did*** have responsibility for making this determination. She purports to find important only what she deems "official" FDA statements on the subject, but she was apparently not informed by Plaintiffs that the FDA had in fact addressed the issue – in a manner that is inconsistent with Trautman's opinion – in at least one communication that she classifies as "official." Nor has she been able to offer a coherent explanation for how her opinion could be justified in the face of consistent contrary views expressed by agency officials. Instead, rather than consider the statements from FDA officials, she bases her opinions on a three-year old report from a Deutsche Bank financial analyst. A Florida court previously excluded as unreliable potential testimony from an FDA expert who relied on the report. Trautman does not even know where the information and opinions in the report came from, and did not do anything to validate its reliability. She identifies no one – including the FDA or any regulated entity – who would turn to financial analysis from Deutsche Bank to interpret FDA regulations.

For all these reasons and as shown in detail below, Trautman's opinions should be excluded.

II. KEY FACTUAL BACKGROUND

Intuitive is the original manufacturer of EndoWrists, surgical instruments cleared by FDA through the 510(k) process. Lazerow Dec. Ex. 1 ¶¶ 16–17. Intuitive submitted extensive life and performance testing to the FDA to provide reasonable assurance of the safety and the effectiveness of EndoWrists. Lazerow Ex. 2 ¶¶ 75–77. The FDA cleared EndoWrists as limited use devices. *Id*.

To avoid the use limits on EndoWrists, third party Rebotix developed an "Interceptor" chip to reset EndoWrists' programmed use limits. *Id.* ¶¶ 167–70; Lazerow Dec. Ex. 1 ¶ 20. Specifically, Rebotix opened up used EndoWrists by brute force, removed the original use counter chip installed by Intuitive, and soldered an Interceptor chip onto the EndoWrist circuit board. Lazerow Dec. Ex. 2 ¶ 170. In December 2014, Rebotix submitted a 510(k) application seeking FDA clearance for this process. Lazerow Dec. Ex. 3 at REBOTIX170424. In that application, Rebotix referred to the "trade name" of its device as a "Re-manufactured EndoWrist." *Id*. "Remanufactured" is an FDA-defined concept linked to the term "remanufacturer," defined by regulation as "any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use." 21 C.F.R. § 820.3(w). In June 2015, FDA issued Rebotix an extensive deficiency letter in which the FDA too referred to Rebotix's process as "remanufacturing." Lazerow Dec. Ex. 4. In December 2015, Rebotix withdrew its 510(k), and the FDA has never cleared the Interceptor chip or Rebotix's process for modifying EndoWrists. Lazerow Dec. Ex. 2 ¶ 171; Lazerow Dec. Ex. 5.

In numerous additional communications to Rebotix and other third parties since 2015 (including in what Trautman deems an "official communication"), FDA has repeatedly and consistently taken the position that modifying EndoWrists to extend their use limits constitutes remanufacturing under FDA regulations that requires 510(k) clearance. *Infra*, §III(A)(3). Indeed, in September 2022, the FDA cleared one entity (Iconocare) to remanufacture one S/Si EndoWrist for an additional 10 uses and created a new medical device classification code for a "surgical instrument for a computer controlled system that 'has been remanufactured to extend its use life as compared to what was originally defined by the original equipment manufacturer.'" Lazerow Dec. Ex. 6 and Ex. 2 ¶¶ 149–152 & fig. 3.

Trautman's opinions relate to the regulatory status of Rebotix and other third parties engaged in modifying EndoWrists to reset their use counters. Lazerow Dec. Ex. 1 ¶ 82. Trautman has been a consultant since 2016. Lazerow Dec. Ex. 1 ¶ 7. From 1991 to 2016, she worked at the FDA. *Id.* ¶¶ 9–13. Her work at FDA concerned primarily "international initiatives," including her most recent FDA

experience (from 2011 to 2016) as the Associate Director for International Programs. *Id*. ¶¶ 9–10, 13, Exhibit A. Trautman never worked in the FDA division that evaluated applications for clearance of medical devices (the Office of Device Evaluation), and thus she has never been a reviewer, or supervisor of reviewers, evaluating submissions known as "510(k) applications." Lazerow Dec. Ex. 7 at 34:20–36:7. During her time as a consumer safety officer and her involvement in FDA enforcement actions, Trautman did not determine whether clearance was required for a company to legally market a device but instead relied on the expertise of others to make those determinations. *Id.* at 73:8–75:15, 79:8–80:8.

Trautman claims she authored the 1996 FDA regulation on good manufacturing practices for medical device manufacturers known as the Medical Device Quality System (QS) regulation, 21 C.F.R. §§ 820 *et seq*. Lazerow Dec. Ex. 1 ¶ 10. That regulation "establishes basic requirements applicable to manufacturers of finished medical devices," including requirements related to "design, manufacture, packaging, labeling, storage, installation, and servicing" medical devices intended for human use. 21 C.F.R. § 820.1(a)(1). Although the QS regulation defines the term "remanufacturer," 21 CFR § 820.3(w), Trautman lacks significant experience applying that definition to specific activities. She had virtually no experience at FDA or as a consultant determining whether specific activities constitutes remanufacturing. Lazerow Dec. Ex. 7 at 21:5–24:10. She has advised only original equipment manufacturers on the topic – a specific circumstance on which the FDA has released clarifying guidance that only applies to manufacturers, not remanufacturers. *Id.* at 23:7–24:10; Lazerow Dec. Ex. 8 at 6 ("This guidance will aid ***manufacturers*** of medical devices . . . who intend to modify a 510(k)-cleared device[.]") (emphasis added). Prior to this case, she had no experience with da Vinci Surgical Systems or EndoWrists. Lazerow Dec. Ex. 7 at 31:18–32:2, 32:15–20. And ultimately a different regulation – the 510(k) regulation, 21 CFR §§ 807 *et seq*. – governs the 510(k) approval process, including when clearance is required. *Id.* at 341:19–24.

III. ARGUMENT

The party proffering expert testimony has the burden of showing the testimony is admissible. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 592 n. 10 (1993). Opinions from a qualified expert

are admissible only to "help the trier of fact to understand the evidence or determine a fact in issue." Fed. R. Evid. 702(a). Expert opinions on questions of law are not helpful to the factfinder because they invade the "exclusive province of the trial judge." *Mannick v. Kaiser Found. Health Plan, Inc.*, 2006 WL 1626909, at *17 (N.D. Cal. June 9, 2006). Thus, "[a]n expert witness cannot give an opinion as to her *legal conclusion*, *i.e.*, an opinion on an ultimate issue of law." *Nationwide Transp. Fin. v. Cass Info. Sys., Inc.*, 523 F.3d 1051, 1058 (9th Cir. 2008) (emphasis original). Opinions that "apply agency law to the facts of [the] case" and purport to describe "the parties' legal rights, duties, and obligations under the law" are inadmissible and must be excluded. *Id.*; *see also Blair v. Shinseki*, 2015 WL 12743841, at *8 (C.D. Cal. Apr. 29, 2015), *aff'd*, 685 F. App'x 587 (9th Cir. 2017) (excluding "legal conclusion" testimony because "[i]nterpretation of . . . regulations and policies is a question for the Court").

The Rules of Evidence permit opinion testimony only from experts qualified by specialized knowledge and "sufficient expertise." *United States v. Morales*, 108 F.3d 1031, 1038 (9th Cir. 1997). In cases where expert testimony would be useful "to help the jury digest [a] complex regulatory framework," the witness's expertise must include "sufficient exposure to and implementation of" the specific regulations at issue. *United States v. Pac. Gas & Elec. Co.*, 2016 WL 3268994, at *2 (N.D. Cal. June 15, 2016). The expert's opinions must be based on sufficient facts or data, the product of reliable principles and methods, and reliably applied to the facts of the case. Fed. R. Evid. 702. Opinions without adequate explanation must be excluded because the court cannot determine whether an expert's methods are reliable. *United States v. Hermanek*, 289 F.3d 1076, 1094 (9th Cir. 2002). Opinions that ignore "a substantial set of facts" and are instead based "only on what appears to be plaintiff-curated records" are also inadmissible. *Smith v. Ill. Dep't of Transp.*, 936 F.3d 554, 558–59 (7th Cir. 2019); *see also In re Bextra & Celebrex Mktg. Sales Pracs. & Prod. Liab. Litig.*, 524 F. Supp. 2d 1166, 1176–77 (N.D. Cal. 2007) (experts cannot offer opinions derived from "cherry-picking" favorable evidence "and rejecting or ignoring the great weight of the evidence that contradicts [their] conclusion").

A. Trautman's Opinion Regarding the Definition of "Remanufacturer" Is Inadmissible For Multiple Reasons.

Trautman's opinion that third party activities modifying EndoWrists to allow them to be used beyond their cleared number of uses do not qualify as "remanufacturing" – and thus do not require FDA clearance – is inadmissible for three reasons: (1) the opinion amounts to an inadmissible legal conclusion, (2) Trautman is not qualified to give the opinion, and (3) the opinion is unreliable.

1. Trautman's Opinion is an Inadmissible Legal Opinion.

Trautman's opinion violates the well-established principles that prohibit an expert from testifying to a legal conclusion.[2] Entire sections of Trautman's Rule 26(a)(2) reports read like legal briefs: she opines that a third party that modifies an EndoWrist "does not meet the definition of 'remanufacturer' as defined in 21 [C.F.R.] § 820.3(w);" that "compliance with the Quality System regulation 21 [C.F.R.] § 820 [and] other FDA regulations" is not required; and that third parties who modify EndoWrists are wholly unregulated "unless or until FDA either promulgates . . . a regulation or notifies [third parties] officially of a more definite legal opinion or regulatory requirement." Lazerow Dec. Ex. 1 ¶¶ 82–83. This is not appropriate testimony for an expert witness.

Faced with similar proffered testimony in the lawsuits brought by Rebotix and Restore, the federal courts in Florida excluded legal opinion testimony from FDA regulatory experts on whether their actions in modifying EndoWrists required FDA clearance. The Court in *Rebotix Repair Inc. v. Intuitive Surgical, Inc.* ("*Rebotix*") ruled that two FDA experts could not give "ultimate legal opinion[s] as to Rebotix's compliance with regulatory requirements" or espouse their "own personal interpretations of

[2] Intuitive accepts that, insofar as Plaintiffs' experts or other witnesses are not permitted to offer opinion testimony on legal issues, Intuitive's witnesses will not be permitted to do so either. Unlike Trautman, however, Intuitive's FDA expert, Christy Foreman, has applied her expertise in FDA policies, processes, and procedures to the objective evidence in the record in order to opine that ***the FDA*** has determined that modifying EndoWrists to reset their use counters is a remanufacturing activity that requires 510(k) clearance. Lazerow Decl. Ex. 2 at ¶ 16(b)(iii) ("Objective and publicly available evidence demonstrates that ***FDA*** has determined that removing or extending the usage limitation on EndoWrist instruments is a remanufacturing activity, and as such, it requires 510(k) clearance.") (emphasis added). Unless the Court opens the door to experts offering legal opinions on these issues, Intuitive would not expect to offer any opinions by Foreman that go beyond explanations of the FDA's own decisions, which are offered to rebut the inadmissible legal opinions of Trautman.

relevant regulations to the extent they differ from the FDA's public interpretations." Lazerow Dec. Ex. 9 at 8, 16. Likewise, the Court in *Restore Repair Inc. v. Intuitive Surgical, Inc.* ("*Restore*") noted that the "role of the Court is to determine the law regarding 510(k) clearance and instruct the jury what was required of Plaintiffs under the law." Lazerow Dec. Ex. 10 at 9.

Trautman offers the same kind of legal opinion testimony excluded in *Rebotix* and *Restore*: that a company that modifies EndoWrist instruments to extend their use limits beyond which they were cleared is not engaged in "remanufacturing" activities that would require FDA clearance. As shown below, the evidence from the FDA compels the conclusion that the agency has determined that the modification of an EndoWrist to extend its use limits constitutes remanufacturing and requires FDA clearance. However, even if the FDA had not made such a determination, it would still be the province of this Court – not an expert or the jury – to make that legal determination.

2. Trautman Is Not Qualified to Opine Whether Modifying an EndoWrist to Extend the Number of Uses Constitutes Remanufacturing.

Trautman lacks "sufficient expertise" to opine on whether the activities at issue in this case qualify as "remanufacturing" under 21 C.F.R. § 820.3(w) or require clearance under the 510(k) regulation, 21 C.F.R §§ 807 *et seq*. None of Trautman's experience relates to determining whether a company is a "remanufacturer," whether modifications made by a third party to a particular medical device require FDA clearance, or whether clearance should be granted on the basis of a particular 510(k) application. She did not make those determinations at FDA or as a consultant. In her few years as a consultant, remanufacturing issues have not been a "major focus" of her work, and she has worked only with original equipment manufacturers (who are by definition required to comply with the Quality System regulation, and who can rely on specially-issued FDA guidance to determine whether changes to their own devices require 510(k) clearance). Lazerow Dec. Ex. 7 at 29:6–25. Trautman thus has virtually no pertinent exposure and implementation experience with the issues on which she opines in this case, and she has provided no information to suggest that her far more significant work on international issues provides her with the necessary qualifications to opine as an expert on whether third parties modifying EndoWrists to add uses need 510(k) clearance to do so.

The law is clear that "a person qualified to give an opinion on one subject is not necessarily qualified to opine on others." *Rogers v. Raymark Indus., Inc.*, 922 F.2d 1426, 1431 (9th Cir. 1991). Trautman may be qualified to opine on other subjects – *e.g.*, the differences and similarities between good manufacturing practices in the United States and foreign countries or whether a particular company's quality management system is adequate. But those issues are not relevant to this case. Trautman lacks sufficient expertise to opine on the application of the 510(k) regulation to third parties engaged in modifying EndoWrists and whether those activities quality as "servicing" or "remanufacturing." Her opinion should therefore be excluded on this ground.

3. Trautman's Opinion Is Not Reliable.

Even if she were not offering a legal conclusion and possessed sufficient relevant expertise to offer opinions on the specific regulatory issues involved here, Trautman's opinions are too unreliable to be admitted for numerous reasons. *First*, in preparing her opening report, Trautman ignored all of FDA's statements on the topic. Although she reviewed a long exchange of communications between the FDA and Rebotix, she does not address any of the statements by ***FDA officials*** in the exchange, including the following statements that expressly contradict her conclusions:

- "[T]he Agency believes that the activities of Rebotix constitute remanufacturing and would require FDA review and clearance (e.g. 510(k) / de Novo)";
- "We therefore request that Rebotix stop engaging in the current activities until an application is reviewed and cleared/granted";
- "The instruments in question no longer maintain the same safety and effectiveness profile as cleared with the original manufacturer's own submission"; and
- "By extending the number of uses and modifying the instrument with a new chip, the prior information is no longer valid and requires additional review to the new labeled usage limit in order to establish safety and effectiveness."

Lazerow Dec. Ex. 11 at Intuitive-00706086;[3] *cf.* Lazerow Dec. Ex. 1 ¶¶ 32–33. Additionally, she did not review or consider numerous other statements by FDA officials on the subject, including:

[3] Trautman insists that these statements are not final, "official" FDA assessments. She does not, however, address the fact that FDA officials repeatedly reiterated these statements – never saying

- In June 2015, in response to Rebotix's 510(k) application ***referring to itself as a remanufacturer*** and identifying its device as a "re-manufactured EndoWrist," the FDA used the term "remanufacture" (or a version of it) ***84 times*** in a deficiency letter to Rebotix. Lazerow Dec. Exs. 3, 4.

- In June 2018, after a distributor for Rebotix asked the FDA why the agency insisted on 510(k) clearance for EndoWrists modified with reset use counters if the company was simply "repairing" the devices, an FDA reviewer explained that resetting the device use counter qualifies as remanufacturing and requires 510(k) clearance. Lazerow Dec. Ex. 12.

- In February 2020, a biomedical engineer on FDA's Robotic Assisted Surgery Devices Team sent emails to Rebotix and Rebotix distributor Restore Robotics that, based on the information on their websites, the FDA believes "that a 510(k) is needed before you continue your operation." Lazerow Dec. Ex. 13 at Intuitive-00706024, Intuitive-00706038. The Robotic Assisted Surgery Devices Team later sought an internal consult from an FDA consumer safety officer, who recommended that activities to extend the "life and function" of EndoWrists "significantly change the devices' intended use, ***constitute remanufacturing***, and ***require premarket notification review to legally market***." *Id*. at Intuitive-00706073 (emphasis added).

- In a March 2022 deficiency letter to Iconocare, FDA made clear that, since the company was seeking to extend the useful life of one S/Si EndoWrist beyond the 10 uses designed by Intuitive, the modified device is "considered a remanufactured device" and asked the company to include "Remanufactured by" and "Not Affiliated with Original Mfr." on the device housing. Lazerow Dec. Ex. 15 at AHP000534–35.[4]

Confronted with these statements, Trautman now insists that only the "formal position" of the FDA is relevant to her and that her analysis focused only on "any official type of communications." Lazerow Dec. Ex. 7 at 156:12–157:13; *see also* Lazerow Dec. Ex. 16 ¶ 12. As an example of such a communication from FDA, she offered "any type of[] It Has Come To Our Attention letter." Lazerow Dec. Ex. 7 at 156:12–157:13. Yet Trautman did not know that FDA ***has*** in fact sent exactly what she was looking for – an official "It Has Come to Our Attention" letter – to Rebotix in November 2021, in which the agency yet again expressed concern about Rebotix's "remanufacturing" activities. Lazerow Dec. Ex. 17; *see also* Lazerow Dec. Ex. 7 at 158:15–159:14, 236:3–237:5.

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anything different – even as they informed Rebotix of procedural routes available to seek an official agency decision. *See* Lazerow Decl. Ex. 14 at REBOTIX175712. Nor does she address the fact that there is no record evidence that FDA ***ever***, in any way, referred to third party modifications to EndoWrists as "servicing" or an activity exempt from 510(k) requirements.

[4] Significantly, ***all*** of these statements came from FDA officials who – unlike Trautman in her prior employment by the agency – had responsibility for making this kind of determination.

Trautman also ignored other FDA actions that contradict her opinion. For example, in conjunction with clearance of Iconocare's 510(k) for a single remanufactured Si EndoWrist, the FDA created a new product code for remanufactured EndoWrists indicating that 510(k) clearance is required. Lazerow Dec. Ex. 2 ¶¶ 149–52 & Fig. 3; Lazerow Dec. Ex. 7 at 316:16–317:20. FDA guidance indicates that the creation of a product code means that "the proposed device differs significantly from the predicate device with respect to technology, intended use or indications." Lazerow Dec. Ex. 18 § 2(C).

Trautman's reliance on Plaintiff-curated records and cherry-picked facts, and her failure to address or explain the overwhelming body of evidence that FDA officials have for nearly a decade consistently interpreted FDA regulations in a manner that directly contradicts her opinions, renders her testimony inadmissible. *See Bextra*, 524 F. Supp. 2d at 1176 (excluding opinion formed by "cherry-picking" supportive facts "and rejecting or ignoring the great weight of the evidence that contradicts [the] conclusion"); *Hermanek*, 289 F.3d at 1094 (collecting cases for the proposition that experts must "explain the reasoning and methods underlying their conclusions").

Second, Trautman points to Intuitive's own attempts to comply with FDA regulations as proof that Rebotix and Restore's modifications to EndoWrists "do not constitute a significant change to the device's performance or safety specifications" sufficient to make those companies "remanufacturers." Lazerow Dec. Ex. 1 ¶ 82(2); Lazerow Dec. Ex. 16 ¶¶ 45–46. That assessment completely ignores important factual and regulatory differences between Intuitive and third parties. Trautman never explains why Intuitive's conclusion that it, as the ***original manufacturer*** of 510(k)-cleared EndoWrists, could program ***new X/Xi*** EndoWrists with a larger number of lives by following a "Note to File" procedure (rather than seeking a full new 510(k) clearance), has any bearing on the activities of ***third parties*** in modifying ***used S/Si*** EndoWrists to bypass their use counters so that the instruments would continue to operate past their cleared use limits. She does not even attempt to explain how the official FDA guidance Intuitive relied upon – which applies on its face only to original "***manufacturers*** of medical devices," *see* Lazerow Dec. Ex. 8 – has any bearing on remanufacturers like Rebotix and

Restore.[5] Trautman acknowledged this guidance in her report, *see* Lazerow Dec. Ex. 1 ¶ 68 & n.50, but answers none of these questions.

Of greatest significance, Trautman simply ignores the fact that the FDA told Intuitive it was ***wrong*** to believe that it did not need 510(k) clearance to assign more lives to some of its devices. *See* Lazerow Dec. Exs. 19, 20. If Trautman's logic here is that Rebotix and Restore should not have needed 510(k) clearance if Intuitive did not need it in this particular instance, the fact that Intuitive ***did*** need 510(k) clearance even under these special circumstances refutes her conclusion on its own terms.

Third, instead of relying on numerous actual statements by the FDA over many years, Trautman relies almost exclusively on statements in a February 2020 report from a Deutsche Bank financial analyst that, in evaluating Intuitive's financial outlook, offered a series of opinions on whether third parties must have FDA clearance to modify EndoWrists to extend the number of uses beyond which they were cleared. *See* Lazerow Dec. Ex. 1 ¶¶ 34–35, 45–46, 60, 81; Lazerow Dec. Ex. 21. The *Rebotix* court excluded expert testimony from another FDA expert who relied on the Deutsche Bank report on the basis that the report was unreliable. *See* Lazerow Decl. Ex. 9 at 15. That holding was plainly correct.

The Deutsche Bank report was written for "institutional investors" and "portfolio managers at mutual funds [and] hedge funds" to "provide intelligence and recommendations around [Intuitive's] stock price." Lazerow Dec. Ex. 22 at 38:12–16, 37:7–25. It was ***not*** written to provide FDA regulators or regulated parties with information essential to weighing the safety, efficacy, or regulatory status of activities to modify complex medical devices. Notably, the Deutsche Bank report does not cite – and there is no evidence its authors or their so-called regulatory experts were even aware of – the numerous communications by FDA, discussed above, confirming that third party modifications to EndoWrists are remanufacturing that require 510(k) clearance. Trautman has not explained why she nevertheless found

[5] Trautman also ignores the fact that Intuitive was extending the number of uses through software programming for original devices that had not yet been sold. Third parties like Rebotix were breaking open used EndoWrists, removing a component, and adding a new component to cause the device to exceed its FDA-cleared use count – a process that on its face constitutes remanufacturing of an existing device.

the Deutsche Bank report significant for her opinions about the FDA's legal regime, much less why it could be more significant than the views of FDA reviewers themselves.

There is also no basis on which Trautman, or this Court, can assess the reliability of the Deutsche Bank report. Trautman claims that she relied on the Deutsche Bank report because "five different independent experts" allegedly interviewed for the report corroborated her opinion, but those so-called "experts" are not identified in the report, and Trautman does not know who they were, what their backgrounds were, how Deutsche Bank qualified them as "experts," or what information they had access to. Lazerow Dec. Ex. 7 at 160:12–164:18; *see also* Lazerow Dec. Ex. 22 at 92:7–14, 144:11–145:9, 194:23–196:10. Experts are generally given wide latitude to choose the sources on which they rely, but courts must nevertheless "examine the reliability of these sources." *Riverside Apartments of Cocoa, LLC v. Landmark Am. Ins. Co.*, 2020 WL 8184710, at *3 (M.D. Fla. Dec. 4, 2020). A financial analyst report, on its face, is ***not*** an authoritative source one can rely upon in interpreting medical device regulations.

Worse, Trautman does not merely rely on facts or data in the report. *See* Lazerow Dec. Ex. 1 ¶¶ 34, 45, 60, 81. Rather, she repeats the opinions of unnamed, unidentified people quoted in the report for the sole purpose of claiming those opinions as her own. *See, e.g.*, *id.* ¶¶ 34–35, 45–46 ("concurring" with Deutsche Bank report). That "analysis" is either an *ipse dixit* logical fallacy or a blatant attempt to end run the Rules of Evidence. *See State Farm Fire & Cas. Co. v. Electrolux Home Prod., Inc.*, 980 F. Supp. 2d 1031, 1048 (N.D. Ind. 2013) ("Rule 703 was not intended to abolish the hearsay rule and to allow a witness, under the guise of giving expert testimony, to in effect become the mouthpiece of the witnesses on whose statements or opinions the expert purports to base his opinion."); *Malletier v. Dooney & Bourke, Inc.*, 525 F. Supp. 2d 558, 666 (S.D.N.Y. 2007) ("[A] party cannot call an expert simply as a conduit for introducing hearsay under the guise that the testifying expert used the hearsay as the basis of his testimony.").

B. Trautman's Opinion Regarding "Commercial Distribution" Is An Inadmissible Legal Opinion.

Trautman also opines that the activities of Rebotix and Restore (which involved modifying EndoWrists to which hospital owners retained title) did not constitute "commercial distribution" – another FDA-defined term – and thus did not require FDA clearance. Lazerow Dec. Ex. 1 ¶ 31. This opinion is an inadmissible legal conclusion. Indeed, her legal conclusion flies in the face of controlling precedent.

A device must be in "commercial distribution" to require FDA clearance. 21 C.F.R. § 807.81(a). "Commercial distribution" is "any distribution of a device intended for human use which is held or offered for sale." 21 C.F.R. § 807.3(b). Trautman claims that she is "applying the FD&C Act[6] and the 510(k) regulation (21 [C.F.R.] § 807) to the activities of Rebotix and Restore." Lazerow Dec. Ex. 1 ¶ 30. In her rebuttal report, Trautman further develops her legal analysis of "commercial distribution" to conclude that "without taking ownership or becoming involved in the sale or resale of such serviced or refurbished device, [third parties'] activities do not meet the regulatory threshold of an entity placing a medical device into interstate commerce for commercial distribution." Lazerow Dec. Ex. 16 ¶ 8(b); *see also id.* ¶¶ 31, 58–59, 81.

Trautman arrived at her opinion without considering that Rebotix and Restore had made the exact same argument to the FDA, to no avail.[7] More importantly, her opinion directly contradicts Ninth Circuit precedent that interprets the key part of the definition of "commercial distribution" – "held for sale" – quite broadly. *See United States v. Kaplan*, 836 F.3d 1199, 1208–11 (9th Cir. 2016). In

[6] The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq*.

[7] *See, e.g.*, Lazerow Dec. Ex. 13 at Intuitive-00706080 (Rebotix: "There is never any sale or resale …. There is also never change of ownership."); *id.* at Intuitive-00706037 (Restore: "We do not sell any medical devices or take ownership of any medical devices sent to us for repairs."). It is unsurprising that FDA never agreed with Restore and Rebotix because FDA stopped making "ownership" a criteria in regulatory determinations in 1998. *See* 63 Fed. Reg. 67076, at 67077 (Dec. 4, 1998) ("FDA no longer believes that the processing, remarketing, or servicing of used devices should be characterized in terms of whether or not the processor acquires ownership of the device for purposes of resale or remarketing. FDA now believes that it may be more appropriate to identify and distinguish between the types of processing conducted on used devices on the basis of whether or not significant changes occur, or are made, in the performance or safety specifications or intended use of the finished device, as a result of the processing.").

interpreting a comparable section of the statute, the Ninth Circuit found that this phrase is not limited to a "sale in the strict sense." *Id.* at 1209. Instead, it covers a "commercial actor in a commercial setting, using a commercial product" intended for use to treat patients. *Id.* at 1210 ("patients who paid Kaplan for the medical services he performed were also paying for the cost of products used in the course of treatment, including biopsies, and that the patients were therefore the ultimate consumers of the guides"). The Court also cited the purpose of the FDCA and the broader statute at issue as supporting its conclusion. *Id.* ("This interpretation of 'held for sale' comports with Congress's intent that the FDCA be interpreted broadly."). Trautman conceded that Rebotix and Restore were engaged in for-profit, commercial activities and that the modified EndoWrists are for use to treat patients, not for personal consumption. Lazerow Dec. Ex. 7 at 126:11–128:19. This case law further confirms that Trautman is offering a legal opinion that invades the "exclusive province of the trial judge." *Mannick*, 2006 WL 1626909, at *17; *Nationwide Transp. Fin.*, 523 F.3d at 1058 ("expert witness cannot give an opinion as to her legal conclusion"); *Blair*, 2015 WL 12743841, at *8 (interpretation of "regulations and policies is a question for the Court").

CONCLUSION

For the foregoing reasons, the Court should exclude Trautman's opinions that third parties modifying EndoWrists to extend their use limits are not "remanufacturers," need not seek 510(k) clearance, and are not engaged in "commercial distribution."

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